

What is claimed is:

1. A composition suitable for administering a therapeutic dose of a corticosteroid to the respiratory tract, consisting essentially of:

- (a) from 5 μ g/ml to about 5 mg/ml of a corticosteroid in dissolved form;
- (b) from about 0.1 to about 20 percent by weight of a pharmaceutically acceptable, high-HLB surfactant component, wherein the HLB of the surfactants present in the high-HLB surfactant component is greater than about 10, and wherein the high-HLB surfactant component comprises at least 50% by weight of an ethoxylated derivative of vitamin E; and
- (c) at least about 70 weight percent aqueous phase.

2. Cancel.

3. Cancel.

4. Cancel.

5. The composition of claim 1 wherein the corticosteroid comprises beclomethasone dipropionate.

6. The composition of claim 1 wherein the corticosteroid comprises budesonide.

7. The composition of claim 1 wherein the corticosteroid comprises triamcinolone acetonide.

RECEIVED 9/14/351
RECEIVED 26 JAN 2000

- 26 -

8. The composition of claim 1 wherein the corticosteroid comprises fluticasone propionate.

9. The composition of claim 1 wherein the corticosteroid comprises flunisolide.

10. The composition of claim 1 wherein the high-HLB surfactant component comprises at least 50% by weight tocopheryl polyethylene glycol 1000 succinate.

11. Cancel.

12. A composition suitable for administering a therapeutic dose of a corticosteroid to the respiratory tract, comprising:

- (a) from 5 μ g/ml to about 5 mg/ml of a corticosteroid in dissolved form;
- (b) from about 0.1 to about 20 percent by weight of a high-HLB surfactant component wherein the HLB of the surfactants present in the high-HLB surfactant component is greater than about 10, and wherein the high-HLB surfactant component comprises at least 50 percent by weight of an ethoxylated derivative of vitamin E; and
- (c) at least about 70 weight percent aqueous phase.

13. The composition of claim 12 wherein the high-HLB surfactant component comprises at least 75 percent by weight of an ethoxylated derivative of vitamin E.

14. The composition of claim 12 wherein the high-HLB surfactant component comprises at least 90 percent by weight of an ethoxylated derivative of vitamin E.

AMENDED SHEET

15. The composition of claim 12 further comprising from about 0.1 to about 20 percent by weight of a pharmaceutically acceptable cosolvent comprising propylene glycol, polyethylene glycol having a molecular weight between about 200 and 4000, glycerol, ethoxydiglycol, glycofurol, and ethanol, or a combination thereof.

16. The composition of claim 12 further comprising from about 0.1 to about 3 percent by weight of a low HLB surfactant having an HLB below about 8.

17. The composition of claim 12 further comprising from about 0.1 to about 3 percent by weight of an oil.

18. A method for administering a therapeutic dosage of a corticosteroid to the respiratory tract, comprising:

- (a) providing a corticosteroid composition comprising:
 - (1) from 5 μ g/ml to about 5 mg/ml of a corticosteroid in dissolved form;
 - (2) from about 0.1 to about 20 percent by weight of a high-HLB surfactant component wherein the HLB of the surfactants present in the high-HLB surfactant component is greater than about 10, and wherein the high-HLB surfactant component comprises at least 50 percent by weight of an ethoxylated derivative of vitamin E; and
 - (3) at least about 70 weight percent aqueous phase;
- (b) aerosolizing the corticosteroid composition; and
- (c) administering a therapeutic effective dosage of the aerosol of the corticosteroid composition by inhalation.

19. The method of claim 18 wherein the corticosteroid composition consists essentially of said corticosteroid, said aqueous phase, and said high-HLB surfactant.

99/14351
26 JAN 2008

- 28 -

20. A method for administering a therapeutic dosage of a corticosteroid to the nasal passage, comprising:

- (a) providing a corticosteroid composition comprising:
 - (1) from about 50 $\mu\text{g/ml}$ to about 10 mg/ml of a corticosteroid in dissolved form;
 - (2) from about 0.1 to about 20 percent by weight of a high-HLB surfactant component wherein the HLB of the surfactants present in the high-HLB surfactant component is greater than about 10, and wherein the high-HLB surfactant component comprises at least 50 percent by weight of an ethoxylated derivative of vitamin E; and
 - (3) at least about 70 weight percent aqueous phase;
- (b) administering a therapeutic effective dosage of the corticosteroid composition by nasal inhalation.

21. A method of preparing a diluted corticosteroid composition containing the corticosteroid in a dissolved form, comprising:

- (a) dissolving a corticosteroid compound into a molten pharmaceutically acceptable high-HLB surfactant component, wherein the HLB of the surfactants present in the high-HLB surfactant component is greater than about 10, and wherein the high-HLB surfactant component comprises at least 50 percent by weight of an ethoxylated derivative of vitamin E;
- (b) subsequently blending the molten high-HLB surfactant component containing the dissolved corticosteroid with an aqueous phase,
wherein the aqueous phase is present in an amount of at least about 70 weight percent, and the high-HLB surfactant component is present in an amount of from about 0.1 to about 20 weight percent of the diluted corticosteroid composition.

28/1

POUS 99/14351
IPAU 26 JAN 2000

-28/1-

22. The composition of claim 1 wherein the ethoxylated derivative of vitamin E comprises at least 75% by weight of the high-HLB surfactant component.

23. The composition of claim 1 wherein the ethoxylated derivative of vitamin E comprises at least 90% by weight of the high-HLB surfactant component.

24. The composition of claim 1 wherein the high-HLB surfactant component comprises at least 75% by weight tocopheryl polyethylene glycol 1000 succinate.

25. The composition of claim 1 wherein the high-HLB surfactant component comprises at least 90% by weight tocopheryl polyethylene glycol 1000 succinate.

26. The composition of claim 12 wherein the high-HLB surfactant component comprises at least 75% by weight tocopheryl polyethylene glycol 1000 succinate.

27. The composition of claim 12 wherein the high-HLB surfactant component comprises at least 90% by weight tocopheryl polyethylene glycol 1000 succinate.

28. The method of claim 18 wherein the ethoxylated derivative of vitamin E comprises at least 75% by weight of the high-HLB surfactant component.

29. The method of claim 18 wherein the high-HLB surfactant component comprises at least 75% by weight tocopheryl polyethylene glycol 1000 succinate.

30. The method of claim 20 wherein the ethoxylated derivative of vitamin E comprises at least 75% by weight of the high-HLB surfactant component.

31. The method of claim 20 wherein the high-HLB surfactant component comprises at least 75% by weight tocopheryl polyethylene glycol 1000 succinate.

AMENDED SHEET

28/2

~~28/2~~

99/14351
26 JAN 2000

32. The method of claim 21 wherein the ethoxylated derivative of vitamin E comprises at least 75% by weight of the high-HLB surfactant component.

33. The method of claim 21 wherein the high-HLB surfactant component comprises at least 75% by weight tocopheryl polyethylene glycol 1000 succinate.